**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**



KERYX BIOPHARMACEUTICALS, INC., PANION & BF BIOTECH, INC. and CHEN HSING HSU,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No. 1:19-CV-40 (Kleeh)

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Keryx Biopharmaceuticals, Inc. ("Keryx"), Panion & BF Biotech, Inc. ("Panion") and Chen Hsing Hsu ("Dr. Hsu") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan"), allege as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, arising from Mylan's submission of Abbreviated New Drug Application ("ANDA") No. 212834 ("Mylan's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Keryx's AURYXIA® (Ferric Citrate) Tablets ("Mylan's Proposed Product") prior to the expiration of United States Patent Nos. 5,753,706 (the "'706 patent"); 7,767,851 (the "'851 patent"); 8,093,423 (the "'423 patent"); 8,299,298 (the "'298 patent"); 8,338,642 (the "'642 patent"); 8,609,896 (the "'896 patent"); 8,754,257 (the "'257 patent"); 8,754,258 (the "'258 patent"); 8,846,976 (the "'976 patent"); 8,901,349 (the "'349

patent"); 9,050,316 (the "'316 patent"); 9,328,133 (the "'133 patent"); 9,387,191 (the "'191 patent"); and 9,757,416 (the "'416 patent") (collectively, the "patents-in-suit"), owned by Plaintiffs.

**THE PARTIES**

2. Plaintiff Keryx is a corporation organized and existing under the laws of Delaware with a principal place of business at One Marina Park Drive, Twelfth Floor, Boston, Massachusetts 02210.

3. Plaintiff Panion is a corporation organized and existing under the laws of Taiwan, with its principal place of business at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan.

4. Plaintiff Dr. Hsu is an individual residing at 2244 Hot Oak Ridge Street, Las Vegas, Nevada 89134.

5. On information and belief, Mylan is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**THE PATENTS-IN-SUIT**

6. On May 19, 1998, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '706 patent, entitled, "Methods for Treating Renal Failure." The '706 patent is assigned to Dr. Hsu. Keryx is the exclusive licensee of all rights in the '706 patent that are relevant to this litigation. A copy of the '706 patent is attached hereto as Exhibit A.

7. On August 3, 2010, the USPTO duly and lawfully issued the '851 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '851 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '851 patent that are relevant to this litigation. A copy of the '851 patent is attached hereto as Exhibit B.

8. On January 10, 2012, the USPTO duly and lawfully issued the '423 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Method of Making Same." The '423 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '423 patent that are relevant to this litigation. A copy of the '423 patent is attached hereto as Exhibit C.

9. On October 30, 2012, the USPTO duly and lawfully issued the '298 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Method of Making Same." The '298 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '298 patent that are relevant to this litigation. A copy of the '298 patent is attached hereto as Exhibit D.

10. On December 25, 2012, the USPTO duly and lawfully issued the '642 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '642 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '642 patent that are relevant to this litigation. A copy of the '642 patent is attached hereto as Exhibit E.

11. On December 17, 2013, the USPTO duly and lawfully issued the '896 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '896 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '896 patent that are relevant to this litigation. A copy of the '896 patent is attached hereto as Exhibit F.

12. On June 17, 2014, the USPTO duly and lawfully issued the '257 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '257 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '257 patent that are relevant to this litigation. A copy of the '257 patent is attached hereto as Exhibit G.

13. On June 17, 2014, the USPTO duly and lawfully issued the ’258 patent, entitled, “Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’258 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the ’258 patent that are relevant to this litigation. A copy of the ’258 patent is attached hereto as Exhibit H.

14. On September 30, 2014, the USPTO duly and lawfully issued the ’976 patent, entitled, “Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’976 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the ’976 patent that are relevant to this litigation. A copy of the ’976 patent is attached hereto as Exhibit I.

15. On December 2, 2014, the USPTO duly and lawfully issued the ’349 patent, entitled, “Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’349 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the ’349 patent that are relevant to this litigation. A copy of the ’349 patent is attached hereto as Exhibit J.

16. On June 9, 2015, the USPTO duly and lawfully issued the ’316 patent, entitled, “Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’316 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the ’316 patent that are relevant to this litigation. A copy of the ’316 patent is attached hereto as Exhibit K.

17. On May 3, 2016, the USPTO duly and lawfully issued the ’133 patent, entitled, “Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’133 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the ’133 patent that are relevant to this litigation. A copy of the ’133 patent is attached hereto as Exhibit L.

18. On July 12, 2016, the USPTO duly and lawfully issued the ’191 patent, entitled, “Ferric Citrate Dosage Forms.” The ’191 patent is assigned to Keryx. A copy of the ’191 patent

is attached hereto as Exhibit M.

19. On September 12, 2017, the USPTO duly and lawfully issued the '416 patent, entitled "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '416 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '416 patent that are relevant to this litigation. A copy of the '416 patent is attached hereto as Exhibit N.

## THE AURYXIA® (FERRIC CITRATE) DRUG PRODUCT

20. Keryx holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for ferric citrate, 210 mg tablets (NDA No. 205874), which it sells under the trade name AURYXIA®. AURYXIA® is an orally available, absorbable, iron-based medicine. AURYXIA® is FDA-approved for the control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis, and for the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis. The claims of the patents-in-suit cover, among other things, novel forms of ferric citrate, methods of controlling phosphate retention, methods of decreasing serum calcium levels, and methods of treating hyperphosphatemia.

21. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to AURYXIA®.

## JURISDICTION AND VENUE

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

23. On information and belief, Mylan has submitted, caused to be submitted, or aided

and abetted in the preparation of Mylan's ANDA. On information and belief, upon FDA approval of Mylan's ANDA, Mylan intends to commercially manufacture, import, market, offer for sale, and/or sell Mylan's Proposed Product throughout the United States including in this district.

24. This Court has personal jurisdiction over Mylan because of, among other things, its systematic and continuous contacts with the State of West Virginia. On information and belief, Mylan is a corporation organized and existing under the laws of West Virginia and has its principal place of business in West Virginia. On information and belief, Mylan regularly and continuously transacts business within West Virginia, including by making and selling pharmaceutical products in West Virginia. On information and belief, Mylan derives substantial revenue from the sale of those products in West Virginia and has availed itself of the privilege of conducting business within West Virginia. On information and belief, Mylan derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

25. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), including because, among other things, Mylan is subject to personal jurisdiction in this judicial district, as set forth above; resides in this judicial district because it is organized under the laws of West Virginia and has its principal place of business in this judicial district; and has a regular and established place of business in this judicial district and has committed acts of infringement and, upon information and belief, will commit further acts of infringement in this judicial district.

**ACTS GIVING RISE TO THIS SUIT**

26. Pursuant to Section 505 of the FFDCA, Mylan filed Mylan's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product before the patents-in-suit expire.

27. On information and belief, following FDA approval of Mylan's ANDA, Mylan will

manufacture, use, offer to sell, or sell Mylan's Proposed Product throughout the United States, or import such generic products into the United States.

28. On information and belief, in connection with the filing of its ANDA as described above, Mylan provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Mylan's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Mylan's ANDA.

29. No earlier than February 1, 2019, Mylan sent written notice of its Paragraph IV Certification to Plaintiffs ("Mylan's Notice Letter"). Mylan's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Mylan's ANDA. Mylan's Notice Letter also informed Plaintiffs that Mylan seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Mylan's Proposed Product before the patents-in-suit expire. Plaintiffs received Mylan's Notice Letter no earlier than February 4, 2019.

30. In Mylan's Notice Letter, Mylan offered to provide access to certain confidential information and materials within Mylan's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Mylan's offer of confidential access was conditioned on terms identified in Mylan's Notice Letter. The terms and conditions of Mylan's offer of confidential access were unreasonable and beyond those that would apply under a protective order. The restrictions Mylan sought to impose on access to its ANDA contravened 21 U.S.C. § 355(j)(5)(C)(i)(III). Plaintiffs notified Mylan that its offer of confidential access did not comply with 21 U.S.C. § 355(j)(5)(C)(i)(III) on February 21, 2019. Despite Mylan's non-compliance with the Hatch-Waxman Act, the parties further communicated about the terms of such confidential access but did not reach agreement. To date, Mylan has not

provided any portion of its ANDA to Plaintiffs.

31. This Complaint is being filed before expiration of the forty-five days from the date Plaintiffs received Mylan's Notice Letter.

**COUNT I**
**Infringement of the '706 Patent**

32. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1 to 31 as if fully set forth herein.

33. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the expiration of the '706 patent, constitutes infringement of one or more of the claims of the '706 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claims 1 and 6.

34. A justiciable controversy exists between the parties hereto as to the infringement of the '706 patent.

35. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '706 patent under at least 35 U.S.C. § 271(a), such as, for example, claim 6, by making, using, offering to sell, selling, and/or importing Mylan's Proposed Product in the United States.

36. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will actively induce infringement of one or more claims of the '706 patent under 35 U.S.C. § 271(b), such as, for example, claim 1, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Mylan's Proposed Product in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement by others, including but not limited to

healthcare providers and patients, with knowledge of the '706 patent and with knowledge that its acts are encouraging infringement.

37. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '706 patent under 35 U.S.C. § 271(c), such as, for example, claim 1, by offering to sell, selling, and/or importing Mylan's Proposed Product in the United States. Mylan's Proposed Product is a material for use in practicing methods claims in the '706 patent that constitutes a material part of those claims' inventions. On information and belief, Mylan knew and knows that Mylan's Proposed Product is especially made or adapted for use in infringing one or more claims of the '706 patent and that Mylan's Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

38. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan's infringement of the '706 patent is not enjoined.

39. Plaintiffs do not have an adequate remedy at law.

40. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT II**
**Infringement of the '851 Patent**

41. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

42. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the expiration of the '851 patent, constitutes infringement of one or more of the claims of the '851 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claim 1.

43. A justiciable controversy exists between the parties hereto as to the infringement of the '851 patent.

44. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '851 patent under at least 35 U.S.C. § 271(a), such as, for example, claim 1, by making, using, offering to sell, selling, and/or importing Mylan's Proposed Product in the United States.

45. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan's infringement of the '851 patent is not enjoined.

46. Plaintiffs do not have an adequate remedy at law.

47. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT III**
**Infringement of the '423 Patent**

48. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

49. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the expiration of the '423 patent, constitutes infringement of one or more of the claims of the '423 patent under 35 U.S.C. § 271(e)(2)(A), such as, for example, claim 7.

50. A justiciable controversy exists between the parties hereto as to the infringement of the '423 patent.

51. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will actively induce infringement of one or more claims of the '423 patent under 35 U.S.C. § 271(b), such as, for example, claim 7, by encouraging others, including but not limited to healthcare

providers and patients, to use, offer for sale, sell, or import Mylan's Proposed Product in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '423 patent and with knowledge that its acts are encouraging infringement.

52. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '423 patent under 35 U.S.C. § 271(c), such as, for example, claim 7, by offering to sell, selling, and/or importing Mylan's Proposed Product in the United States. Mylan's Proposed Product is a material for use in practicing methods claims in the '706 patent that constitutes a material part of those claims' inventions. On information and belief, Mylan knew and knows that Mylan's Proposed Product is especially made or adapted for use in infringing one or more claims of the '423 patent, and that Mylan's Proposed Product is not a staple article or commodity with a substantial non-infringing use.

53. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan's infringement of the '423 patent is not enjoined.

54. Plaintiffs do not have an adequate remedy at law.

55. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT IV**
**Infringement of the '298 Patent**

56. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

57. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the

expiration of the ’298 patent, constitutes infringement of one or more of the claims of the ’298 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claim 1.

58. A justiciable controversy exists between the parties hereto as to the infringement of the ’298 patent.

59. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will infringe one or more claims of the ’298 patent under at least 35 U.S.C. § 271(a), such as, for example, claim 1, by making, using, offering to sell, selling, and/or importing Mylan’s Proposed Product in the United States.

60. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan’s infringement of the ’298 patent is not enjoined.

61. Plaintiffs do not have an adequate remedy at law.

62. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

**COUNT V**
**Infringement of the ’642 Patent**

63. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

64. Mylan’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan’s Proposed Product, prior to the expiration of the ’642 patent, constitutes infringement of one or more of the claims of the ’642 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claims 1, 8, 10, and 17.

65. A justiciable controversy exists between the parties hereto as to the infringement of

the ’642 patent.

66. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will infringe one or more claims of the ’642 patent under at least 35 U.S.C. § 271(a), such as, for example, claims 1 and 10, by making, using, offering to sell, selling, and/or importing Mylan’s Proposed Product in the United States.

67. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will actively induce infringement of one or more claims of the ’642 patent under 35 U.S.C. § 271(b), such as, for example, claims 8 and 17, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Mylan’s Proposed Product in the United States. On information and belief, upon FDA approval of Mylan’s ANDA, Mylan will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the ’642 patent and with knowledge that its acts are encouraging infringement.

68. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will contributorily infringe one or more claims of the ’642 patent under 35 U.S.C. § 271(c), such as, for example, claims 8 and 17, by offering to sell, selling, and/or importing Mylan’s Proposed Product in the United States. Mylan’s Proposed Product is a material for use in practicing methods claims in the ’706 patent that constitutes a material part of those claims’ inventions. On information and belief, Mylan knew and knows that Mylan’s Proposed Product is especially made or adapted for use in infringing one or more claims of the ’642 patent, and that Mylan’s Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

69. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan’s infringement of the ’642 patent is not enjoined.

70. Plaintiffs do not have an adequate remedy at law.

71. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT VI**
**Infringement of the '896 Patent**

72. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

73. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the expiration of the '896 patent, constitutes infringement of one or more of the claims of the '896 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claim 1.

74. A justiciable controversy exists between the parties hereto as to the infringement of the '896 patent.

75. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '896 patent under at least 35 U.S.C. § 271(a), such as, for example, claim 1, by making, using, offering to sell, selling, and/or importing Mylan's Proposed Product in the United States.

76. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan's infringement of the '896 patent is not enjoined.

77. Plaintiffs do not have an adequate remedy at law.

78. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT VII**
**Infringement of the ’257 Patent**

79. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

80. Mylan’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan’s Proposed Product, prior to the expiration of the ’257 patent, constitutes infringement of one or more of the claims of the ’257 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claim 1.

81. A justiciable controversy exists between the parties hereto as to the infringement of the ’257 patent.

82. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will infringe one or more claims of the ’257 patent under at least 35 U.S.C. § 271(a), such as, for example, claim 1, by making, using, offering to sell, selling, and/or importing Mylan’s Proposed Product in the United States.

83. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan’s infringement of the ’257 patent is not enjoined.

84. Plaintiffs do not have an adequate remedy at law.

85. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

**COUNT VIII**
**Infringement of the ’258 Patent**

86. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

87. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the expiration of the '258 patent, constitutes infringement of one or more of the claims of the '258 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claim 1.

88. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.

89. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '258 patent under at least 35 U.S.C. § 271(a), such as, for example, claim 1, by making, using, offering to sell, selling, and/or importing Mylan's Proposed Product in the United States.

90. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan's infringement of the '258 patent is not enjoined.

91. Plaintiffs do not have an adequate remedy at law.

92. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT IX**
**Infringement of the '976 Patent**

93. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

94. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the expiration of the '976 patent, constitutes infringement of one or more of the claims of the '976 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such

as, for example, claim 1.

95. A justiciable controversy exists between the parties hereto as to the infringement of the '976 patent.

96. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will actively induce infringement of one or more claims of the '976 patent under 35 U.S.C. § 271(b), such as, for example, claim 1, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Mylan's Proposed Product in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '976 patent and with knowledge that its acts are encouraging infringement.

97. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '976 patent under 35 U.S.C. § 271(c), such as, for example, claim 1, by offering to sell, selling, and/or importing Mylan's Proposed Product in the United States. Mylan's Proposed Product is a material for use in practicing methods claims in the '706 patent that constitutes a material part of those claims' inventions. On information and belief, Mylan knew and knows that Mylan's Proposed Product is especially made or adapted for use in infringing one or more claims of the '976 patent, and that Mylan's Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

98. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan's infringement of the '976 patent is not enjoined.

99. Plaintiffs do not have an adequate remedy at law.

100. This case is an exceptional one, and Plaintiffs are entitled to an award of their

reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT X**
**Infringement of the '349 Patent**

101. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

102. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the expiration of the '349 patent, constitutes infringement of one or more of the claims of the '349 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claim 1.

103. A justiciable controversy exists between the parties hereto as to the infringement of the '349 patent.

104. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will actively induce infringement of one or more claims of the '349 patent under 35 U.S.C. § 271(b), such as, for example, claim 1, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Mylan's Proposed Product in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '349 patent and with knowledge that its acts are encouraging infringement.

105. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '349 patent under 35 U.S.C. § 271(c), such as, for example, claim 1, by offering to sell, selling, and/or importing Mylan's Proposed Product in the United States. Mylan's Proposed Product is a material for use in practicing methods claims in

the ’706 patent that constitutes a material part of those claims’ inventions. On information and belief, Mylan knew and knows that Mylan’s Proposed Product is especially made or adapted for use in infringing one or more claims of the ’349 patent, and that Mylan’s Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

106. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan’s infringement of the ’349 patent is not enjoined.

107. Plaintiffs do not have an adequate remedy at law.

108. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

**COUNT XI**
**Infringement of the ’316 Patent**

109. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

110. Mylan’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan’s Proposed Product, prior to the expiration of the ’316 patent, constitutes infringement of one or more of the claims of the ’316 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claim 1 .

111. A justiciable controversy exists between the parties hereto as to the infringement of the ’316 patent.

112. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will actively induce infringement of one or more claims of the ’316 patent under 35 U.S.C. § 271(b), such as, for example, claims 1 and 12, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Mylan’s Proposed Product

in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '316 patent and with knowledge that its acts are encouraging infringement.

113. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '316 patent under 35 U.S.C. § 271(c), such as, for example, claim 1, by offering to sell, selling, and/or importing Mylan's Proposed Product in the United States. Mylan's Proposed Product is a material for use in practicing methods claims in the '706 patent that constitutes a material part of those claims' inventions. On information and belief, Mylan knew and knows that Mylan's Proposed Product is especially made or adapted for use in infringing one or more claims of the '316 patent, and that Mylan's Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

114. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan's infringement of the '316 patent is not enjoined.

115. Plaintiffs do not have an adequate remedy at law.

116. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT XII**
**Infringement of the '133 Patent**

117. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

118. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the expiration of the '133 patent, constitutes infringement of one or more of the claims of the '133

patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claims 1, 8, 10, and 17.

119. A justiciable controversy exists between the parties hereto as to the infringement of the '133 patent.

120. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '133 patent under at least 35 U.S.C. § 271(a), such as, for example, claims 1 and 10, by making, using, offering to sell, selling, and/or importing Mylan's Proposed Product in the United States.

121. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will actively induce infringement of one or more claims of the '133 patent under 35 U.S.C. § 271(b), such as, for example, claims 8 and 17, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Mylan's Proposed Product in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '133 patent and with knowledge that its acts are encouraging infringement.

122. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '133 patent under 35 U.S.C. § 271(c), such as, for example, claims 8 and 17, by offering to sell, selling, and/or importing Mylan's Proposed Product in the United States. Mylan's Proposed Product is a material for use in practicing methods claims in the '706 patent that constitutes a material part of those claims' inventions. On information and belief, Mylan knew and knows that Mylan's Proposed Product is especially made or adapted for use in infringing one or more claims of the '133 patent, and that Mylan's Proposed

Product is not a staple article or commodity of commerce with a substantial non-infringing use.

123. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan's infringement of the '133 patent is not enjoined.

124. Plaintiffs do not have an adequate remedy at law.

125. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT XIII**
**Infringement of the '191 Patent**

126. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

127. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the expiration of the '191 patent, constitutes infringement of one or more of the claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claims 1, 6, 11 and 16.

128. A justiciable controversy exists between the parties hereto as to the infringement of the '191 patent.

129. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '191 patent under at least 35 U.S.C. § 271(a), such as, for example, claims 1, 6, 11 and 16, by making, using, offering to sell, selling, and/or importing Mylan's Proposed Product in the United States.

130. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan's infringement of the '191 patent is not enjoined.

131. Plaintiffs do not have an adequate remedy at law.

132. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT XIV**
**Infringement of the '416 Patent**

133. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-31 as if fully set forth herein.

134. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Product, prior to the expiration of the '416 patent, constitutes infringement of one or more of the claims of the '416 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claims 1 and 23.

135. A justiciable controversy exists between the parties hereto as to the infringement of the '416 patent.

136. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will actively induce infringement of one or more claims of the '416 patent under 35 U.S.C. § 271(b), such as, for example, claims 1 and 23, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Mylan's Proposed Product in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '416 patent and with knowledge that its acts are encouraging infringement.

137. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '416 patent under 35 U.S.C. § 271(c), such as, for example, claims 1 and 23, by offering to sell, selling, and/or importing Mylan's Proposed

Product in the United States. Mylan's Proposed Product is a material for use in practicing methods claims in the '706 patent that constitutes a material part of those claims' inventions. On information and belief, Mylan knew and knows that Mylan's Proposed Product is especially made or adapted for use in infringing one or more claims of the '416 patent, and that Mylan's Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

138. Plaintiffs will be substantially and irreparably damaged and harmed if Mylan's infringement of the '416 patent is not enjoined.

139. Plaintiffs do not have an adequate remedy at law.

140. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Mylan has infringed the patents-in-suit by submitting ANDA No. 212834 to the FDA;

B. A Declaratory Judgment under 28 U.S.C. § 2201 that Mylan's commercial manufacture, use, offer to sell, sale, or importation Mylan's Proposed Product will infringe one or more claims of the patents-in-suit;

C. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of FDA approval of ANDA No. 212834 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Mylan, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Mylan's Proposed

Product, or from actively inducing or contributing to the infringement of claims of the patents-in-suit, until after the expiration of the patents-in-suit or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. A Declaratory Judgment under 28 U.S.C. § 2201 that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Mylan's Proposed Product will directly infringe, induce, and/or contribute to infringement of the patents-in-suit;

F. To the extent that Mylan has committed any acts with respect to the devices, compositions, formulations, and methods of use and administration claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts, together with interest;

G. If Mylan engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Mylan's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

H. A Declaratory Judgment under 28 U.S.C. § 2201 that the patents-in-suit remain valid and enforceable;

I. A Judgment finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees incurred in this action;

J. A Judgment awarding Plaintiffs their costs and expenses incurred in this action; and

L. Such further and other relief as this Court may deem just and proper.

Dated: March 15, 2019

THOMAS COMBS & SPANN, PLLC

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